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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,643	03/20/2002	Richard Fayrer-Hosken	235.00300101	1109

26813 7590 05/15/2007

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ART UNIT	**PAPER NUMBER**
1644	

MAIL DATE	DELIVERY MODE
05/15/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/019,643	FAYRER-HOSKEN ET AL.	
	Examiner	Art Unit	
	Michael Szperka	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4,6,12-15,17-19,21,27-29 and 42-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4,6,12-15,17-19,21,27-29 and 42-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's response and amendments received February 26, 2007 are acknowledged.

Claims 1-3, 5, 7-11, 16, 20, 22-26, and 30-41 have been canceled.
Claims 6 and 29 have been amended.
Claims 4, 6, 12-15, 17-19, 21, 27-29, and 42-47 are pending.

Claims 4, 6, 12-15, 17-19, 21, 27-29, and 42-47 are under examination as they read on methods of administering immunogenic compositions comprising avian and non-avian zona pellucida proteins.

2. As part of the response to the office action mailed September 26, 2006, applicant has included remarks concerning the length of prosecution and the appropriateness of rejections set forth under both 35 USC 112 and 103. These remarks were made separately and as part the specific responses to the rejections of record. As such, these issues will be addressed first and will not be further addressed with the rejections of record.

Applicant first expresses concern about the length of prosecution, argues that full faith and credit has not been given to the search and actions of the former examiner, and argues "that the enablement of the presently claimed methods has been repeatedly acknowledged by the U.S. Patent and Trademark Office during the prolonged prosecution of the present application."

These arguments are not persuasive because the length of prosecution is not material to patentability, and the office reserves the right to correct any errors that may arise during the course of prosecution. Further, the new grounds of rejection set forth in the office action mailed 9/26/06 were required because applicant amended the scope of the claimed invention such that the art and rejections of record made by the former examiner were no longer applicable.

Applicant's second argument is that it is inappropriate to simultaneously set forth rejections under 35 USC 112 1st paragraph enablement and 35 USC 103(a).

This argument is not persuasive because there is no statutory bar that if a rejection is made under one statute, another rejection cannot be made under a different statute. The courts have ruled that enablement and art are distinct issues, stating in *Rasmusson v. SmithKlein Beecham Corp.,* 75 USPQ2d 1297 (CAFC 2005), that:

> "The standard for what constitutes proper enablement of a prior art reference for purposes of anticipation under section 102, however, differs from the enablement standard under section 112. In *In re Hafner*, 410 F.2d 1403 161 USPQ 783 (CCPA 1969), the court stated that "a disclosure lacking a teaching of how to use a fully disclosed compound for a specific, substantial utility or of how to use for such purpose a compound produced by a fully disclosed process is, under the present state of the law, entirely adequate to anticipate a claim to either the product or the process and, at the same time, entirely inadequate to support the allowance of such a claim." *Id.* at 1405; *see Schoenwald*, 964 F.2d at 1124; *In re Samour*, 571 F.2d 559, 563-64 197 USPQ 1 (CCPA 1978). The reason is that section 112 "provides that the specification must enable one skilled in the art to 'use' the invention whereas [section] 102 makes no such requirement as to an anticipatory disclosure." *Hafner*, 410 F.2d at 1405; *see* 1 Donald S. Chisum, *Chisum on Patents* §3.04[1][c] (2002); *see also In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1349-52 64 USPQ2d 1202_ (Fed. Cir. 2001) (finding anticipation where applicant sought a patent based on a new use for a previously disclosed method)."

As such there are instances where it is appropriate to reject claims under art that also lack enablement.

In the instant case, based on the teachings of the prior art it appears that administering ZP antigens causes immunocontraception and immunosterility in animals due to autoimmune oophoritis. As such, administering the compositions recited in the instant methods would be expected to induce autoimmune oophoritis in animals receiving said compositions. Autoimmune oophoritis is a reproductive disease, yet the claim preamble recites that a disease is treated or prevented by performing the claimed method. This contradiction is addressed most appropriately under 35 USC 112 1st paragraph. However, a skilled artisan would have been motivated to perform the recited method steps prior to the time the instant invention was made because administering ZP antigens causes immunocontraception and immunosterilization, and thus rejections were also set forth under 35 USC 103(a).

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 4, 6, 12-15, 17, 18, 21, 23, 28, 29, and 41-47 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the reasons of record.

The office action mailed 9/26/06 states:

> Independent claim 4 recites a method for treating diseases "related to" egg production or egg laying. How are these diseases related since any disease can be "related to" something else in some manner? Are the diseases caused by egg production or is some other mechanism involved? Dependent claim 6 recites limitations that address some of these issues, but such limitations are not present in any other claim that depends directly or indirectly from claim 4.
>
> Dependent claim 6 recites "cloacal problems" and "undesirable behavior as a result of reproductive activity or reproductive problems." What are cloacal problems? What behaviors are undesirable, and how do these behavior result from reproductive activity or problems? Is sexual promiscuity an undesirable behavior that results from reproductive activity? Do birds exhibit depression as a result of infertility and lack of egg production?
>
> Claims 28 and 47 recite "wherein the immunogenic conjugate is dually functional" but the two functions of the immunoconjugate are not recited. As such, what are the functions that the immunocongugate comprises? It is noted that the specification exemplifies, but does not define, "dually functional" conjugates from line 20 of page 11 to line 15 of page 12. Therefore, a skilled artisan is not apprised of the metes and bounds of the claimed invention.
>
> Claim 29 recites "A method for affecting the reproductive system of a bird" by administering a composition, but the claim does not recite the effect caused by said administration. How is the reproductive system altered by performing applicant's method? Is reproductive activity increased, decreased, eliminated, or altered in some unspecified way by applicant's method?

Applicant's arguments filed February 26, 2007 have been fully considered but they are not persuasive. Applicant first argues that "diseases, disorders and conditions related to egg production or egg laying" are well understood to ordinary artisans involved in the veterinary care and animal husbandry of birds. Applicant further indicates that dependent claim 6 recites specific conditions, and that the prior examiner of record did not find the instant claim language objectionable under the present statute.

This argument is not persuasive because applicant has provided argument, but not evidence, that a skilled artisan would understand the instant claim language. Applicant is reminded that as per MPEP 2145, "Attorney argument is not evidence unless it is an admission, in which case, an examiner may use the admission in making a rejection. See MPEP § 2129 and § 2144.03 for a discussion of admissions as prior

art. The arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997) ("An assertion of what seems to follow from common experience is just attorney argument and not the kind of factual evidence that is required to rebut a prima facie case of obviousness."). See MPEP § 716.01(c) for examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration." The limitations of claim 6 do not apply to any claims other than claim 6 itself, and as such claim 6 cannot be said to specify the disorders, diseases and conditions recited in the independent claims. Additionally, the withdrawal of a rejection under 35 USC 112 first paragraph by the previous examiner of record when the claims were amended on March 16, 2005 to recite "method for treating or preventing a reproductive disease, disorder, or condition related to egg production..." is not evidence that a rejection under 35 USC 112 2nd paragraph, or under any other statute, is inappropriate since the office reserves the right to correct any errors that occur during prosecution prior to issuance of a patent to ensure the proper patentability of the claimed subject material.

Applicant also argues that the claim 6 has been amended to remove the recitation of "cloacal problems", that the metes and bounds of "undesirable behavior" are well known, and that this language was present in the original claims, and that no rejections concerning this language were set forth until the prior office action.

This argument is not convincing because while the removal of the recitation of "cloacal problems" has rendered that issue moot, the metes and bounds of "undesirable behavior" are not clear. Applicant has pointed to page 18, lines 23-27 to indicate how "undesirable behavior" is to be interpreted, but this passage is exemplification, not a definition of "undesirable behavior". "Undesirable behavior is broader than what is disclosed in the aforementioned passage, but what it encompasses is not clear. The fact that it is an original claim limitation means that the limitation is not new matter, but does not mean that a skilled artisan would know what the limitation means. As discussed supra, failure of former examiner of record to identify all issues material to patentability is not evidence that such issues do not exist.

Applicant also argues that "dually functional" is clear, that it is an original claim limitation, and points to page 11, lines 24-31 for guidance in the specification. This argument is not convincing. Page 11 discloses:

> "A dually functional conjugate refers to a zona pellucida protein, or fragment thereof, conjugated to one independently protective carrier protein, and a multiply functional conjugate refers to a zona pellucida protein, or fragment thereof, conjugated to two or more independently protective carrier proteins, or to a single carrier protein or protein construct that is capable of eliciting two or more independently protective immune responses. The carrier protein is advantageously selected to elicit immunological protection against an infection or disease state to which the intended subject may be exposed."

Note that a "dually functional" construct must mount two independent immune responses, but the specificity of such responses is not clear because the immune response that is independent of an anti-zona pellucida response is not required to be specific for an infection or disease state. Further, what are the infections or disease states, especially given that applicant is claiming that zona pellucida antigens are involved in "disease states"? The issue of the claim language being original and never before rejected has been discussed above and will not be discussed further.

Applicant argues that claim 29 has been amended to recite a "method of treating or preventing a reproductive disease, disorder, or condition..." thus rendering moot the issues of "affecting the reproductive system".

This argument is not persuasive because while applicant's claim amendments do remove the issues of "affecting the reproductive system", the amended claim language is that of independent claim 4. The metes and bounds of such a recitation are not clear for the same reasons as discussed above in conjunction with claim 4.

The rejection is maintained.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 4, 6, 12-15, 17-19, 21, 27-29, and 42-47 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims

contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for the reasons of record.

The office action mailed 9/26/06 states:

> Applicant has claimed a method for treating or preventing reproductive diseases and disorders by administering a composition comprising avian and non-avian zona pellucida (ZP) proteins to birds. The specification prophetically teaches that administering said composition induces the production of antibodies that bind to the zona pellucida proteins present on eggs (example VIII), and that the presence of anti-ZP antibodies in an animal cause either temporary or permanent sterility (see particularly the paragraph spanning pages 17 and 18). Diseases taught by the specification as being amenable to prevention or treatment by the instant claimed methods include those recited in dependent claim 6.
>
> Prevention requires that applicant's claimed method works in 100% of animals 100% of the time. As stated above, the specification does not provide a working example wherein a composition comprising avian and non-avian ZP was administered to a bird, and as such there is no evidence of record that performing applicant's method can prevent any reproductive disease.
>
> Administration of an immunogenic composition comprising avian and non-avian ZP proteins as per applicant's method elicits the production of antibodies that bind the ZP proteins present in the ovaries of the immunized bird. ZP proteins are important for the binding of sperm to eggs. The presence of these antibodies can have many effects, ranging from inhibition of sperm binding to eggs due to steric hindrance up to autoimmune-mediated destruction of ovarian tissue (Mahi-Brown et al., Birth Control Vaccines, 1995, pages 41-61, see entire document, and see the paragraph spanning pages 17 and 18 of the instant specification). Given that administration of ZP proteins to an animal often leads to ovarian autoimmune disease, it appears that applicant's method causes reproductive disease rather than prevents or treats reproductive diseases.
>
> Further, a review of the art indicates that many of the recited reproductive diseases are caused by infection with bacterial, viral or other pathogenic organisms. Specifically, Shivaprasad teaches that fowl typhoid and pillorum disease are bacterial diseases that cause peritonitis and salpingitis in chickens (Rev. Sci. Tech. 2000, 19:405-424, see particularly the abstract). Salpingitis can also be caused by infections with *Tetratrichomonas, E. coli*, and *Pasteurella multocida* (Crespo et al., J.Vet Diagn. Invest. 2001, 13:240-245, see particularly page 240). Egg-binding is caused by many factors, including lack of tonus or weak tonus of the oviduct or cloacal musculature, pelvic deformations, eggs that are too large, eggs without shells, eggs with soft shells, eggs with rough shells, torsion of the oviduct, systemic infections, infections of the reproductive tract, and genetic factors (Krautwald-Junghanns et al., Vet Rec. 1998, 143:498-502, see particularly the left column of page 499). Cloacal problems, such as cloacal prolapse, can be caused by infection with *Cryptosporidium* (Penrith et al., Onderstepoort J Vet Res. 1994, 61:283-289). Further, cloacal prolapse is known to occur in male birds, and note that egg production and laying are not observed in males (Ibid). Given that many of the diseases recited as reproductive diseases and disorders are caused by microbial infections or physical abnormalities, it is unclear how generation of an anti-ZP protein antibody response in such animals would be of therapeutic benefit.
>
> Therefore, given the breadth of applicant's claimed invention, the lack of a working example comprising administration of a composition comprising both avian and non-avian ZP proteins to a bird, the fact that many of the recited reproductive diseases and disorders are caused by factors not directly linked to egg production or laying, and the fact that administration of ZP proteins often causes the reproductive disease ovarian autoimmunity, a skilled artisan would be unable to practice the breadth of applicant's claimed method without conducting undue research.

Applicant's arguments filed February 26, 2007 have been fully considered but they are not persuasive. Applicant argues that the instant claims are enabled based upon examples III, IV, and VIII.

This argument is not persuasive because example III is concerned with administration of pig ZP to chickens. The instant claimed method recites administering

non-avian and avian ZP to a bird, and as such the scope of example III is not concordant with the claimed invention. Example IV is limited to administering pig ZP to a single bird. Based upon a single example, a skilled artisan cannot tell if the observed affects are due to the administration of the pig ZP or are due to random chance. Example VIII is a prophetic example concerning the administration of pig ZP in combination with avian ZP. Data concerning the efficacy (or lack thereof) for such a method is not present in the specification, nor has such data been supplied during prosecution. As such, the specification does not comprise a working example of the claimed invention.

Applicant also argues that the specification teaches that administering ZP can lead to either immunocontraception or immunosterilization through the production of anti-ZP antibodies, and that a skilled artisan would have a reasonable expectation of success in practicing the claimed invention especially in view of the teachings of Mahi-Brown et al. cited by the current examiner of record in the prior office action.

This argument is not persuasive because it misses the point. Based on the prior art, it does appear that administering ZP antigens causes immunocontraception and immunosterility. However, applicant has claimed a method of treating or preventing a reproductive disease. Eliciting an anti-ZP antibody response in an animal causes an autoimmune disease that destroys the ovary as taught by Mahi-Brown. As such, administering ZP antigen **causes** a reproductive disease (autoimmune oophoritis). Causing a disease is the opposite of treating a disease. Applicant's claims recite preventing and treating diseases, not causing them. Further, while it may be that administering ZP antigens causes immunocontraception and immunosterility, it is not clear that treatment or prevention is possible for all of the conditions recited in claim 6. Indeed, claim 6 recites "oophoritis", a condition that is known to be caused by administering ZP antigens. Applicant does not appear to have addressed this aspect of the rejection of record to any depth.

Applicant further requests that the examiner substantiate the statement of record that the broadest reasonable interpretation of prevention is that it works 100% of the time in 100% of patients.

This argument is not persuasive because applicant has not pointed to a location in the specification where "prevention" is defined. In the absence of a definition in the specification, it has been determined that the broadest reasonable interpretation of "prevention" encompasses 100% efficacy.

The rejection is maintained.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 4, 6, 12-15, 17, 18, 21, 27-29, 42, and 44-47 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Curtiss et al. (US Patent 5,656,488, of record) in view of Harris et al. (US Patent 5,976,545) in view of Mahi-Brown et al. (Birth Control Vaccines, 1995, pages 41-61) and in view of Waclawek et al. (Biology of Reproduction, 1998, 59:1230-1239) for the reasons of record.

The office action mailed 9/26/06 states:

> Curtiss et al. teach reducing or preventing fertilization of eggs in birds by administering a glycoprotein, ZP3, from pigs (see entire document, particularly the paragraph spanning columns 2 and 3, lines 11-22 of column 7). They teach that the administered glycoprotein is naturally occurring, recombinantly made, is to be administered with or without carriers (i.e. avirulent microbes) that are dually functional (since the microbe acts as a carriers and as an immunogen), and is administered with or without adjuvants such as aluminum hydroxide (see particularly lines 44-65 of column 3 and lines 10-34 of column 16). Curtiss et al. further teach that their compositions when administered elicit antibody responses, and as such the compositions minimally comprise B cell epitopes. These teachings differ from the instant claimed invention

in that Curtiss et al. do not teach administering a composition comprising non-avian and avian ZP proteins to a bird.

Harris et al. teach the sequence of ZP proteins from numerous animals, and teach that the ZP proteins administered to an animal must be capable of eliciting an antibody response that reacts with the animal's endogenous ZP proteins to be therapeutically effective (see entire document, particularly column 8).

Mahi-Brown et al. teach that administered ZP proteins are not immunogenic when administered to the same species but are often immunogenic when administered to other species (see particularly the bottom of the right column of page 45). However, while administration of porcine ZP proteins elicits an anti-porcine ZP antibody response in non-porcine animals, these elicited antibodies are known not to crossreact with endogenous ZP proteins in all animals (see particularly the second full paragraph of the right column of page 46).

Waclawek et al. teach the purification and protein sequence of chicken ZP3 (see entire document, particularly Figures 2 and 3).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to add avian ZP proteins to the compositions administered to birds in the methods taught by Curtiss et al. Motivation to do so comes from the teachings of Harris et al. that elicited antibody responses must be capable of crossreacting with endogenous ZP proteins and the teachings of Mahi-Brown that endogenous ZP proteins are not immunogenic and that porcine ZP does not elicit antibodies that crossreact with endogenous ZP proteins in all animals. As such, the presence of porcine ZP protein in the administered composition would ensure that an immune response was generated while the presence of avian ZP protein would ensure that some of the elicited antibody response was directed to endogenous avian ZP proteins.

Applicant's arguments filed February 26, 2007 have been fully considered but they are not persuasive. Applicant argues that the combination of references teaches away from the claimed invention. Specifically, applicant appears to argue that there is no explicit motivation for a skilled artisan to combine the prior art elements into a composition for administration to a bird.

This argument is not found persuasive. The courts have repeatedly ruled that motivation to combine elements can be explicitly or implicitly stated in the prior art or come from common knowledge of an artisan or common sense, and that for patentability, improvements to or combinations of prior at elements must amount to more than the predictable use of the prior art elements according to their established functions. See *KSR Int'l Co. v. Teleflex, Inc.*, 2007. In the instant case, it does not appear that avian and non-avian ZP behave in manner that is not predicted by the teachings of the prior art.

Applicant has stated in the reply that the teachings of Mahi-Brown indicate that ZP proteins are not immunogenic when administered to the same species. This is the reason for administering a non-avian ZP in conjunction with avian ZP. It is well known to skilled artisans that self antigens are not immunogenic, but that immune responses can be generated when self antigens are administered in the presence of an adjuvant.

The use of adjuvants in vaccines is well established in medicine, and administering adjuvants in combination with self antigens is widely used in tumor vaccination. Pig ZP is foreign (and hence antigenic) in birds, and Curtiss teaches administering pig ZP to birds. It is also known in the art that antibodies to pig ZP do not crossreact with ZP antigens of all species. As such, combining avian and pig ZP ensures that an antibody response will be elicited that can bind avian ZP because the pig ZP acts as an adjuvant that leads to the formation of an immune response to the self antigen, namely avian ZP.

As such, a person of ordinary skill in the art at the time the invention was made would have been motivated to combine the teachings of the prior art to arrive at the instant claimed methods for the reasons of record, especially given that it does not appear that the individual components that comprise the compositions administered by the instant claimed methods work in a way that would not be predicted based upon the prior art.

9. Claims 19 and 43 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Curtiss et al. (US Patent 5,656,488, of record) in view of Harris et al. (US Patent 5,976,545) in view of Mahi-Brown et al. (Birth Control Vaccines, 1995, pages 41-61) and in view of Waclawek et al. (Biology of Reproduction, 1998, 59:1230-1239) as applied to claims 4, 6, 12-15, 17, 18, 21, 23, 27-29, 41, 42, and 44-47 above, and further in view of Willis et al. (J. Equine Vet Sci, 1994, 14:364-370) for the reasons of record.
The office action mailed 9/26/07 states:

> The claimed invention differs from the teachings of Curtiss et al., Harris et al., Mahi-Brown et al., and Waclawek et al., in the recitation that the administered composition comprises the adjuvant STDCM.
>
> Willis et al. teach the use of STDMC in methods of vaccinating animals with ZP proteins (see entire document, particularly the first paragraph). STDMC offers an advantage over other adjuvants in that its use does not produce unwanted side effects of vaccination, such as abscess formation at the vaccination site (see particularly the second full paragraph of the left column of page 369).
>
> Therefore, it would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to substitute STDMC for the adjuvant taught in the methods of Curtiss et al. Harris et al. Mahi-Brown et al., and Waclawek et al. Motivation to make this substitution comes from the teachings of Willis et al. that STDMC offers advantages over other adjuvants in that the use of STDMC does not lead to abscess formation at the vaccination site.

Applicant's arguments filed February 26, 2007 have been fully considered but they are not persuasive. Applicant argues that the addition of Willis et al. does not

counteract the deficiencies in the teachings of Curtiss et al., Harris et al., Mahi-Brown et al., and Waclawek et al.

This argument is not persuasive because applicant's objections to combining Curtiss et al., Harris et al., Mahi-Brown et al., and Waclawek et al. have been addressed above and were not found persuasive. Applicant does not argue any additional reasons why the indicated claims are not obvious in view of Willis et al., and as such the rejection is maintained.

Claim Objections

10. The objection to claims 23 and 41 has been withdrawn in light of their cancellation as part of the response received February 26, 2007.

11. No claims are allowable.

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Szperka whose telephone number is 571-272-2934. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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5/11/07

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